



**VALIDATION AND COMPLIANCE PLAN
FOR THE
EXAMPLE VALIDATION SPREADSHEET
SERVING**

**OFNI SYSTEMS
RALEIGH, NORTH CAROLINA**

Ofni Systems

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PREPARED BY
DANIEL WATERMAN
VALIDATION MANAGER
OFNI SYSTEMS

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Ofni Systems can validate all of your software, databases, spreadsheets and computer systems, and develop the appropriate documentation for all phases of the software life cycle. We can provide any level of service required, from executing test scripts generated from your existing specifications to writing the entire validation package. Ofni Systems will perform risk assessments to focus the validation effort on the most appropriate sections of your system.

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Ofni Systems is a leader in providing regulatory compliance solutions for pharmaceutical, biotech and medical device companies. They are the creators of [ExcelSafe for Excel spreadsheet security](#) and the [Part 11 Toolkit for compliant databases](#). They also are the creators of the [FastVal validation software for generating and executing validation documents](#), and have been providing [professional validation services](#) using FastVal since 2006. Their products for Part 11 compliant databases and spreadsheets are used by pharmaceutical, biotech and medical device companies across the globe, while it's products for computer validation, auditing and FDA submissions ensure that their clients meet every requirement for electronic records and electronic signatures.

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SIGNATURES

Author: _____ Signature: _____ Date: _____
System Owner: _____ Signature: _____ Date: _____
Quality Assurance: _____ Signature: _____ Date: _____

REVISION HISTORY

Rev #	Description	Date Approved
0	Initial Issue.	

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1. Introduction

1.1. Objectives

This is the Validation and Compliance Plan for the Example Validation Spreadsheet (VCP-001), for use by Validation Department at Ofni Systems (Raleigh, NC). The Example Validation spreadsheet has been identified a Category 5 cGxP system (customized MS Excel spreadsheet).

The Validation and Compliance Plan for the Example Validation Spreadsheet defines the methodology, deliverables and responsibilities for the validation of the Example Validation Spreadsheet. The Validation and Compliance Plan will also describe criteria for final acceptance of validation deliverables, system release and the controls that Ofni Systems has the controls in place to maintain Example Validation Spreadsheet in a validated state.

1.2. Scope

This Validation and Compliance Plan applies to the Example Validation Spreadsheet. The VCP will define the strategy, risk mitigation, project deliverables and acceptance criteria for the validation of the Example Validation Spreadsheet.

1.3. Assumptions

The validation will be performed on a properly functioning Ofni Systems workstation, with MS Excel and ExcelSafe properly installed.

1.4. Exclusions

This validation applies to the Example Validation spreadsheet, and not to MS Excel, ExcelSafe, the workstation or computer environment.

2. Acronyms and References

2.1. Acronyms and Definitions

Cell - An individual square in a spreadsheet grid.

CFR - Code of Federal (US) Regulations

cGxP - Abbreviation which includes current Good Manufacturing, Clinical and Laboratory Practices

Closed System - An environment in which system access is controlled by persons who are responsible for the content of electronic records that are on the system.

FRS - Functional Requirements Specification

GUI - Graphical User Interface

IOQ - Installation/Operational Qualification

LAN - Local Area Network

Open System - An environment in which system access is not controlled by persons who are responsible for the content of electronic records that are on the system.

SDS - Software Design Specification

SOP - Standard Operating Procedure

Spreadsheet - Generic term for application containing rows and columns of cells, with functions to manipulate data within those cells.

Workbook - A group of one or more worksheets contained within a spreadsheet file. The workbook may also include code modules.

Worksheet - One of possibly multiple data sheets within a workbook.

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2.2. References

21 CFR Part 11 "Electronic Records; Electronic Signatures"

GAMP 5, A Risk-Based Approach to Compliant GxP Computerized Systems

3. Responsibilities

3.1. Project Sponsor

- 3.1.1. Serves as project champion to the business, including communicating the project goals to the business as a whole.
- 3.1.2. Approves the budget, determines budget tolerances and assures availability of essential project resources.
- 3.1.3. Has ultimate authority and responsibility for the project.

3.2. System Owner

- 3.2.1. Provides technical expertise related to system and database design, including specific guidance relative to approach, methodology, etc. as requested.
- 3.2.2. Assists in development and execution of training required by the validation project.
- 3.2.3. Manages the development of system process SOPs and maintains SOPs as appropriate.
- 3.2.4. Reviews and approves of key project deliverables.
- 3.2.5. Performs validation periodic reviews of the validated computer system to ensure it is operated in compliance with all Policies, SOPs, and regulatory requirements and is being maintained in a controlled manner

3.3. Business Owner

- 3.3.1. Ensures that the computer related system meets the business needs of the user departments.
- 3.3.2. Represents the user departments when making critical decisions.
- 3.3.3. Assists in testing to ensure the system is tested properly.
- 3.3.4. Reviews and approves all computer validation and training documentation to ensure that the information is accurate and complete from the business process perspective.
- 3.3.5. Ensures that Standard Operating Procedures are in place for user operations.

3.4. Validation Manager

- 3.4.1. Manages overall project resources and is the point contact for the project.
- 3.4.2. Leads the Validation sub-team in developing validation deliverables, including this Validation Plan and Validation Summary Report
- 3.4.3. Provides specific guidance relative to approach, methodology, etc.
- 3.4.4. Monitors project progress per validation plan.
- 3.4.5. Reviews and approves of key project deliverables.

3.5. Validation Resources

- 3.5.1. Provides Subject Matter expertise on all aspects of the validation project, as required.